

Thomas R. Curtin  
George C. Jones  
GRAHAM CURTIN  
A Professional Association  
4 Headquarters Plaza  
P.O. Box 1991  
Morristown, New Jersey 07962-1991  
(973) 292-1700

*Attorneys for Defendants  
Par Sterile Products, LLC and  
Par Pharmaceutical Companies, Inc.*

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY**

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FRESENIUS KABI USA, LLC,	:	
	:	
	:	Civil Action No. 16-4544 (SDW) (LDW)
Plaintiff,	:	
	:	
v.	:	Hon. Susan D. Wigenton, U.S.D.J.
	:	Hon. Leda Dunn Wettre, U.S.M.J.
	:	
PAR STERILE PRODUCTS, LLC	:	
and PAR PHARMACEUTICAL	:	
COMPANIES, INC.,	:	
	:	<b>JURY TRIAL DEMANDED</b>
Defendants.	:	
	:	

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**DEFENDANTS PAR STERILE PRODUCTS, LLC  
AND PAR PHARMACEUTICAL COMPANIES, INC.’S  
ANSWER AND DEFENSES TO PLAINTIFF’S COMPLAINT**

Defendants Par Pharmaceutical Companies, Inc. and Par Sterile Products, LLC (collectively, “Par”), by and through their attorneys, admit, deny, and aver as follows with respect to Plaintiff’s Complaint, dated July 27, 2016. Unless

specifically admitted, Par denies each and every allegation and denies liability to Plaintiff. To the extent that Plaintiff has included headings or impertinent material that are inappropriate under Rules 8 and 12(f) of the Federal Rules of Civil Procedure, no response is necessary and any such inappropriate material should be stricken. In any event, to the extent any headings or inappropriate material are deemed to require a response, Par denies them. Any allegation not expressly and explicitly admitted is denied.

### **NATURE OF THE ACTION**

1. Par avers that to the extent Paragraph 1 of the Complaint states legal conclusions, no response is required. To the extent a response is required, Par denies the allegations in Paragraph 1 of the Complaint.

2. Par denies the allegations in Paragraph 2 of the Complaint, except admits that Par is a pharmaceutical company.

3. Par denies the allegations in Paragraph 3 of the Complaint.

4. Par (i) admits the allegations in the first sentence of Paragraph 4 of the Complaint, (ii) admits that Plaintiff refers to vasopressin injection as “Intravenous Vasopressin Injection” throughout the Complaint, and (iii) avers that it is without knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations in Paragraph 4 and Footnote 1 of the Complaint.

5. Par denies the allegations in Paragraph 5 of the Complaint, except admits that it is an FDA-approved seller of vasopressin injection.

6. Par avers that it is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 6 of the Complaint.

7. Par avers that it is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 7 of the Complaint.

8. Par denies the allegations in Paragraph 8 of the Complaint, except (i) admits that the price for vasopressin injection has changed over time, and (ii) avers that Paragraph 8 purports to describe the contents of third-party written material, and Par respectfully refers the Court to the original material for a true and complete statement of its contents.

9. Par avers that to the extent Paragraph 9 of the Complaint states legal conclusions, no response is required. To the extent a response is required, Par avers that it is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 9 of the Complaint, except denies that a Drug Master File (“DMF”) is essential for an Abbreviated New Drug Application (“ANDA”) or that an ANDA filer must demonstrate that its API supplier has filed a DMF with the FDA in advance of its ANDA submission.

10. Par admits the allegations in Paragraph 10 of the Complaint, except denies that a DMF is essential for an ANDA or that an ANDA filer must demonstrate that its API supplier has filed a DMF with the FDA in advance of its ANDA submission.

11. Par admits that (i) the API used in vasopressin injection is vasopressin, a man-made form of the polypeptide hormone that is normally produced by the pituitary gland, and (ii) based on publicly available information as of the date of this Answer, BCN, Bachem, and PolyPeptide Labs are vasopressin API suppliers with active DMFs. Par further avers that it is without knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations in Paragraph 11 of the Complaint, except denies that a DMF is essential for an ANDA or that an ANDA filer must demonstrate that its API supplier has filed a DMF with the FDA in advance of its ANDA submission.

12. Par denies the allegations in Paragraph 12 of the Complaint.

13. Par denies the allegations in Paragraph 13 of the Complaint, except avers that Paragraph 13 purports to quote written material, and Par respectfully refers the Court to that material for a true and complete statement of its contents.

14. Par denies the allegations in Paragraph 14 of the Complaint.

15. Par avers that to the extent Paragraph 15 of the Complaint states legal conclusions, no response is required. To the extent a response is required, Par

denies the remaining allegations in Paragraph 15 of the Complaint, except admits that (i) the U.S. Patent & Trademark Office issued Patent No. 9,375,478 to Par relating to Vasostrict, and (ii) an ANDA application requires the applicant to identify patents listed in the Orange Book.

16. Par denies the allegations in Paragraph 16 of the Complaint.

17. Par denies the allegations in Paragraph 17 of the Complaint, except avers that Paragraph 17 purports to reference written material, and Par respectfully refers the Court to that material for a true and complete statement of its contents.

18. Par denies the allegations in Paragraph 18 of the Complaint, except avers that Paragraph 18 purports to reference written material, and Par respectfully refers the Court to that material for a true and complete statement of its contents.

19. Par denies the allegations in Paragraph 19 of the Complaint.

### **THE PARTIES**

20. Par avers that it is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 20 of the Complaint.

21. Par admits the allegations in the first, second, and third sentences of Paragraph 21 of the Complaint. Par denies the allegations in the last sentence of Paragraph 21 and avers that Par Sterile's corporate headquarters are located in Chestnut Ridge, New York.

22. Par denies the allegations in Paragraph 22 of the Complaint, except admits that its executive offices are located at One Ram Ridge Road, Chestnut Ridge, New York 10977.

### **JURISDICTION AND VENUE**

23. Par avers that to the extent Paragraph 23 of the Complaint states legal conclusions, no response is required. To the extent a response is required, Par denies the allegations in Paragraph 23.

24. Par avers that it is not required to respond to the allegations in Paragraph 24 of the Complaint because Paragraph 24 states legal conclusions to which no response is required.

25. Par avers that it is not required to respond to the allegations in Paragraph 25 of the Complaint because Paragraph 25 states legal conclusions to which no response is required.

### **RELEVANT MARKET**

#### **A. Relevant Product Market**

26. Par denies the allegations in Paragraph 26 of the Complaint.

27. Par avers it is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 27 of the Complaint, except admits that Vasostriect is an FDA-approved drug indicated to increase blood pressure in adults with vasodilatory shock (e.g., post-cardiotomy or sepsis) who remain hypotensive despite fluids and catecholamines.

28. Par admits the allegations in Paragraph 28 of the Complaint.

29. Par denies the allegations in Paragraph 29 of the Complaint.

30. Par admits the allegations in Paragraph 30 of the Complaint.

31. Par admits the allegations in Paragraph 31 of the Complaint.

32. Par denies the allegations in Paragraph 32 of the Complaint.

**B. Relevant Geographic Market**

33. Par denies the allegations in Paragraph 33 of the Complaint.

**C. Barriers to Entry**

34. Par denies the allegations in Paragraph 34 of the Complaint.

35. Par denies the allegations in Paragraph 35 of the Complaint, except admits that the FDA oversees the pharmaceutical market in the United States, including the development, manufacturing, sales, marketing, and distribution of pharmaceutical products in the United States.

36. Par avers that to the extent Paragraph 36 of the Complaint states legal conclusions, no response is required. To the extent a response is required, Par avers that it is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 36 of the Complaint.

37. Par denies the allegations in Paragraph 37 of the Complaint, except avers that Paragraph 37 purports to reference written material, and Par respectfully refers the Court to that material for a true and complete statement of its contents.

38. Par denies the allegations in Paragraph 38 of the Complaint, except avers that Paragraph 38 purports to reference written material, and Par respectfully refers the Court to that material for a true and complete statement of its contents.

**D. Interstate Commerce**

39. Par avers that it is not required to respond to the allegations in Paragraph 39 of the Complaint because Paragraph 39 states legal conclusions to which no response is required. To the extent a response is required, Par denies the allegations in Paragraph 39 of the Complaint, except admits that it has sold a vasopressin injection product in the United States.

40. Par avers that it is not required to respond to the allegations in Paragraph 40 of the Complaint because Paragraph 40 states legal conclusions to which no response is required. To the extent a response is required, Par denies the allegations in Paragraph 40 of the Complaint.

41. Par avers (i) that it is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 41 of the Complaint, and (ii) that Paragraph 41 purports to reference written material, and Par respectfully refers the Court to that material for a true and complete statement of its contents.



### **ADDITIONAL FACTUAL BACKGROUND**

#### **A. Multiple Competitors Participated In The Intravenous Vasopressin Injection Market Before FDA Approval Was Required**

42. Par avers that it is not required to respond to the allegations in Paragraph 42 of the Complaint because Paragraph 42 states legal conclusions to which no response is required. To the extent a response is required, Par denies the allegations in Paragraph 42 of the Complaint.

43. Par avers that it is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 43 of the Complaint, except admits that vasopressin injection was sold as an unapproved drug prior to Par receiving FDA approval.

44. Par avers that it is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 44 of the Complaint.

45. Par avers (i) that it is not required to respond to the allegations in Paragraph 45 of the Complaint because Paragraph 45 states legal conclusions to which no response is required and (ii) that it is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 45, except admits that Par acquired JHP Pharmaceuticals, LLC which sold vasopressin injection under the name Pitressin, and that JHP Pharmaceuticals, LLC, was renamed Par Sterile Products, LLC.

46. Par avers that it is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 46 of the Complaint, except (i) admits that the FDA has encouraged drug manufacturers to seek FDA approval of unapproved drugs and (ii) avers that Paragraph 46 purports to reference written material, and Par respectfully refers the Court to that material for a true and complete statement of its contents.

47. Par admits that on September 26, 2012, Par submitted to the FDA a New Drug Application (“NDA”) (NDA No. 204485) for Vasopressin, pursuant to Section 505(b)(2) of the FDCA, 21 U.S.C. § 355(b)(2).

**B. Par Becomes The Sole FDA-Approved Manufacturer Of Intravenous Vasopressin Injection**

48. Par avers that it is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations regarding Fresenius Kabi in Paragraph 48. Par denies the remaining allegations in Paragraph 48, except admits that (i) the FDA authorized Par to market and sell Vasopressin in April 2014, (ii) Par commenced selling Vasopressin in November 2014, and (iii) before selling Vasopressin, Par sold Pitressin.

49. Par avers that it is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 49 of the Complaint, except avers that Paragraph 49 purports to reference written material,

and Par respectfully refers the Court to that material for a true and complete statement of its contents.

50. Par denies the allegations in Paragraph 50 of the Complaint, except admits that it filed a Lanham Act suit against Fresenius Kabi, and that the suit was voluntarily dismissed, without prejudice, pursuant to a stipulation between the parties. Par respectfully refers the Court to that complaint for a true and complete statement of its contents.

51. Par denies the allegations in Paragraph 51 of the Complaint.

52. Par admits the allegations in Paragraph 52 of the Complaint, but respectfully refers the Court to the written material referenced therein for a true and complete statement of its contents.

53. Par avers that it is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 53 of the Complaint.

54. Par avers that it is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 54 of the Complaint.

55. Par denies the allegations in Paragraph 55 of the Complaint, except admits that the price of vasopressin injection has changed over time.

56. Par denies the allegations in Paragraph 56 of the Complaint, except avers that Paragraph 56 purports to reference written material, and Par respectfully refers the Court to that material for a true and complete statement of its contents.

57. Par denies the allegations in Paragraph 57 of the Complaint.

**C. Fresenius Kabi Is Prepared And Intends To Re-Enter The Market For Intravenous Vasopressin Injection**

58. Par avers that it is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 58 of the Complaint.

59. Par avers that it is not required to respond to the allegations in Paragraph 59 of the Complaint because Paragraph 59 states legal conclusions to which no response is required.

60. Par avers that it is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 60 of the Complaint.

61. Par avers that it is not required to respond to the allegations in the first sentence of Paragraph 61 of the Complaint because that sentence states legal conclusions to which no response is required. Par further avers that it is without knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations in Paragraph 61 of the Complaint.

62. Par denies the allegations in Paragraph 62 of the Complaint, except admits that DMFs include information regarding API suppliers and their products.

63. Par avers that it is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in the first sentence of Paragraph 63. Par admits the allegations in the last sentence of Paragraph 63 of the Complaint.

64. Par admits the allegations in Paragraph 64 of the Complaint, except denies that a DMF is essential for an ANDA or that an ANDA filer must demonstrate that its API supplier has filed a DMF with the FDA in advance of its ANDA submission.

65. Par denies the allegations in Paragraph 65 of the Complaint, except avers that Paragraph 65 purports to reference written material, and Par respectfully refers the Court to that material for a true and complete statement of its contents.

66. Par admits that vasopressin, a white to off-white powder, freely soluble in water is the API used in making vasopressin injection and denies the remaining allegations in Paragraph 66 of the Complaint.

67. Par avers that it is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 67 of the Complaint, except admits that, based on publicly available information as of the

date of this Answer, BCN, Bachem, and PolyPeptide Labs are vasopressin API suppliers with active DMFs.

68. Par denies the allegations in Paragraph 68 of the Complaint.

69. Par denies the allegations in Paragraph 69 of the Complaint, except avers that Paragraph 69 purports to reference written material, and Par respectfully refers the Court to that material for a true and complete statement of its contents.

70. Par avers that it is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 70 of the Complaint.

### **PAR'S MARKET POWER**

71. Par denies the allegations in Paragraph 71 of the Complaint.

72. Par denies the allegations in Paragraph 72, except admits that it is an FDA-approved seller of vasopressin injection.

73. Par denies the allegations in Paragraph 73 of the Complaint.

### **PAR'S ANTICOMPETITIVE CONDUCT**

#### **A. Par Has Willfully Maintained Its Substantial Market Power Through The Use Of Anticompetitive Exclusionary Conduct**

74. Par denies the allegations in Paragraph 74 of the Complaint.

75. Par denies the allegations in Paragraph 75 of the Complaint.

76. Par avers that it is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 76 of the

Complaint, except admits that, based on publicly available information as of the date of this Answer, BCN, Bachem, and PolyPeptide Labs are vasopressin API suppliers with active DMFs.

77. Par denies the allegations in Paragraph 77 of the Complaint, except avers that it is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegation that Bachem and PolyPeptide Labs are “locked into exclusive contracts for Vasopressin API.”

**1. BCN**

78. Par avers that it is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 78 of the Complaint.

79. Par denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 79 of the Complaint, except admits that BCN has an active DMF for vasopressin API and has supplied Par.

80. Par avers that it is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 80 of the Complaint.

81. Par avers that it is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 81 of the Complaint.

82. Par avers that it is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 82 of the Complaint.

83. Par avers that it is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 83 of the Complaint, except admits that BCN supplied vasopressin API to Par.

84. Par avers that it is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 84 of the Complaint.

85. Par avers that it is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 85 of the Complaint.

86. Par avers that it is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 86 of the Complaint.

87. Par avers that it is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 87 of the Complaint.



88. Par avers that it is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 88 of the Complaint.

89. Par avers that it is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations regarding Fresenius Kabi's business dealings. Par denies the remaining allegations in Paragraph 89 of the Complaint.

90. Par avers that it is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 90 of the Complaint.

91. Par avers that it is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 91 of the Complaint.

92. Par avers that it is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 92 of the Complaint.

93. Par avers that it is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 93 of the Complaint.

94. Par avers that it is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations regarding Fresenius Kabi's business dealings. Par denies the remaining allegations in Paragraph 94 of the Complaint.

95. Par denies the allegations in Paragraph 95 of the Complaint.

96. Par avers that it is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations regarding Fresenius Kabi's business dealings. Par denies the remaining allegations in Paragraph 96 of the Complaint.

97. Par avers that it is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 97 of the Complaint.

98. Par denies the allegations in Paragraph 98 of the Complaint.

99. Par denies the allegations in Paragraph 99 of the Complaint.

## **2. Bachem**

100. Par avers that it is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 100 of the Complaint.

101. Par avers that it is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 101 of the Complaint.

102. Par avers that it is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 102 of the Complaint.

103. Par avers that it is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 103 of the Complaint.

104. Par avers that it is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 104 of the Complaint.

105. Par avers that it is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 105 of the Complaint.

106. Par avers that it is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations regarding Fresenius Kabi's business dealings. Par denies the remaining allegations in Paragraph 106 of the Complaint.

### **3. PolyPeptide Labs**

107. Par avers that it is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 107 of the Complaint except admits that based on publicly available information as of the date of this Answer, PolyPeptide Labs is a vasopressin API supplier with an active DMF.

108. Par avers that it is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 108 of the Complaint.

109. Par avers that it is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 109 of the Complaint.

#### **B. Par's Exclusionary Conduct Results In Substantial Foreclosure Of The Relevant Market**

110. Par denies the allegations in Paragraph 110 of the Complaint.

111. Par avers that it is not required to respond to the allegations in Paragraph 111 of the Complaint because Paragraph 111 states legal conclusions to which no response is required. To the extent a response is required, Par denies the allegations in Paragraph 111 of the Complaint, except admits that it obtained a patent relating to Vasostrict.

112. Par denies the allegations in Paragraph 112 of the Complaint, except avers that Paragraph 112 purports to reference written material, and Par respectfully refers the Court to that material for a true and complete statement of its contents.

113. Par denies the allegations in Paragraph 113 of the Complaint, except avers that Paragraph 113 purports to reference written material, and Par respectfully refers the Court to that material for a true and complete statement of its contents.

114. Par avers (i) that it is without knowledge or information sufficient to form a belief as to the truth or falsity of allegations regarding the purported feelings of investors in Paragraph 114 of the Complaint, and (ii) that Paragraph 114 purports to reference written material, and Par respectfully refers the Court to that material for a true and complete statement of its contents.

115. Par denies the allegations in Paragraph 115 of the Complaint.

116. Par denies the allegations in Paragraph 116 of the Complaint.

117. Par denies the allegations in Paragraph 117 of the Complaint.

118. Par avers that it is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 118 of the Complaint.

119. Par avers that to the extent Paragraph 119 of the Complaint states legal conclusions, no response is required. To the extent a response is required, Par denies the allegations in Paragraph 119 of the Complaint.

120. Par denies the allegations in Paragraph 120 of the Complaint.

**C. Par's Exclusionary Conduct Has Caused Substantial Anti-Competitive Effects**

121. Par denies the allegations in Paragraph 121 of the Complaint.

**1. Par's exclusionary conduct has caused consumers and payors to pay supracompetitive prices for Intravenous Vasopressin Injection and has reduced consumer choice.**

122. Par denies the allegations in Paragraph 122 of the Complaint.

123. Par denies the allegations in Paragraph 123 of the Complaint.

124. Par denies the allegations in Paragraph 124 of the Complaint.

125. Par denies the allegations in Paragraph 125 of the Complaint, except (i) admits that vasopressin injection sales have increased, and (ii) avers that to the extent Plaintiff relied on unidentified written material in constructing the allegations in Paragraph 125, Par respectfully refers the Court to that material for a true and complete statement of its contents.

126. Par denies the allegations in Paragraph 126 of the Complaint.

127. Par denies the allegations in Paragraph 127 of the Complaint, except avers that Paragraph 127 purports to reference written material, and Par

respectfully refers the Court to that material for a true and complete statement of its contents.

**2. Par's exclusionary conduct has injured Fresenius Kabi.**

128. Par denies the allegations in Paragraph 128 of the Complaint.

129. Par denies the allegations in Paragraph 129 of the Complaint.

130. Par avers that it is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 130 of the Complaint.

131. Par avers that it is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 131 of the Complaint.

132. Par avers that it is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 132 of the Complaint.

133. Par denies the allegations in Paragraph 133 of the Complaint.

134. Par avers that it is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations regarding Fresenius Kabi's business dealings in Paragraph 134 of the Complaint. Par denies the remaining allegations in Paragraph 134.

135. Par avers that it is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 135 of the Complaint.

136. Par avers that it is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 136 of the Complaint.

137. Par avers that it is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 137 of the Complaint, except it admits that vasopressin injection was previously sold without approval from the FDA.

138. Par denies the allegations in Paragraph 138 of the Complaint.

139. Par denies the allegations in Paragraph 139 of the Complaint.

140. Par denies the allegations in Paragraph 140 of the Complaint.

141. Par denies the allegations in Paragraph 141 of the Complaint.

142. Par denies the allegations in Paragraph 142 of the Complaint.

**D. Par's Exclusionary Conduct Lacks a Valid Procompetitive Business Justification**

143. Par denies the allegations in Paragraph 143 of the Complaint.

144. Par denies the allegations in Paragraph 144 of the Complaint.

145. Par denies the allegations in Paragraph 145 of the Complaint.



**COUNT I**  
**(MONOPOLIZATION – SHERMAN ACT SECTION 2)**

146. Par reasserts its answers to Paragraphs 1 through 145 of the Complaint.

147. Par denies the allegations in Paragraph 147 of the Complaint, except admits (i) that the price of vasopressin injection has changed over time and (ii) that it is an FDA-approved seller of vasopressin injection.

148. Par denies the allegations in Paragraph 148 of the Complaint.

149. Par denies the allegations in Paragraph 149 of the Complaint.

150. Par denies the allegations in Paragraph 150 of the Complaint.

151. Par denies the allegations in Paragraph 151 of the Complaint.

152. Par denies the allegations in Paragraph 152 of the Complaint.

**COUNT II**  
**(ATTEMPTED MONOPOLIZATION – SHERMAN ACT SECTION 2)**

153. Par reasserts its answers to Paragraphs 1 through 152 of the Complaint.

154. Par denies the allegations in Paragraph 154 of the Complaint.

155. Par denies the allegations in Paragraph 155 of the Complaint.

156. Par denies the allegations in Paragraph 156 of the Complaint.

157. Par denies the allegations in Paragraph 157 of the Complaint.

158. Par denies the allegations in Paragraph 158 of the Complaint.

159. Par denies the allegations in Paragraph 159 of the Complaint.

160. Par denies the allegations in Paragraph 160 of the Complaint.

161. Par denies the allegations in Paragraph 161 of the Complaint.

**COUNT III**  
**(CONSPIRACY TO MONOPOLIZE – SHERMAN ACT SECTION 2)**

162. Par reasserts its answers to Paragraphs 1 through 161 of the Complaint.

163. Par denies the allegations in Paragraph 163 of the Complaint.

164. Par denies the allegations in Paragraph 164 of the Complaint.

165. Par denies the allegations in Paragraph 165 of the Complaint.

166. Par denies the allegations in Paragraph 166 of the Complaint.

167. Par denies the allegations in Paragraph 167 of the Complaint.

168. Par denies the allegations in Paragraph 168 of the Complaint.

169. Par denies the allegations in Paragraph 169 of the Complaint.

**COUNT IV**  
**(EXCLUSIVE DEALING – SHERMAN ACT SECTION 1)**

170. Par reasserts its answers to Paragraphs 1 through 169 of the Complaint.

171. Par denies the allegations in Paragraph 171 of the Complaint.

172. Par denies the allegations in Paragraph 172 of the Complaint.

173. Par denies the allegations in Paragraph 173 of the Complaint.

174. Par denies the allegations in Paragraph 174 of the Complaint.

175. Par denies the allegations in Paragraph 175 of the Complaint.

176. Par denies the allegations in Paragraph 176 of the Complaint.

177. Par denies the allegations in Paragraph 177 of the Complaint.

**COUNT V**  
**(UNLAWFUL GROUP BOYCOTT – SHERMAN ACT SECTION 1)**

178. Par reasserts its answers to Paragraphs 1 through 177 of the Complaint.

179. Par denies the allegations in Paragraph 179 of the Complaint.

180. Par denies the allegations in Paragraph 180 of the Complaint.

181. Par denies the allegations in Paragraph 181 of the Complaint.

182. Par denies the allegations in Paragraph 182 of the Complaint.

183. Par denies the allegations in Paragraph 183 of the Complaint.

184. Par denies the allegations in Paragraph 184 of the Complaint.

185. Par denies the allegations in Paragraph 185 of the Complaint.

186. Par denies the allegations in Paragraph 186 of the Complaint.

187. Par denies the allegations in Paragraph 187 of the Complaint.

**COUNT VI**  
**(MONOPOLIZATION – NEW JERSEY ANTITRUST ACT)**

188. Par reasserts its answers to Paragraphs 1 through 187 of the Complaint.

189. Par denies the allegations in Paragraph 189 of the Complaint, except admits (i) that the price of vasopressin injection has changed over time and (ii) that it is an FDA-approved seller of vasopressin injection.

190. Par denies the allegations in Paragraph 190 of the Complaint.

191. Par denies the allegations in Paragraph 191 of the Complaint.

192. Par denies the allegations in Paragraph 192 of the Complaint.

193. Par denies the allegations in Paragraph 193 of the Complaint.

194. Par denies the allegations in Paragraph 194 of the Complaint.

**COUNT VII**  
**(ATTEMPTED MONOPOLIZATION – NEW JERSEY ANTITRUST ACT)**

195. Par reasserts its answers to Paragraphs 1 through 194 of the Complaint.

196. Par denies the allegations in Paragraph 196 of the Complaint.

197. Par denies the allegations in Paragraph 197 of the Complaint.

198. Par denies the allegations in Paragraph 198 of the Complaint.

199. Par denies the allegations in Paragraph 199 of the Complaint.

200. Par denies the allegations in Paragraph 200 of the Complaint.

201. Par denies the allegations in Paragraph 201 of the Complaint.

202. Par denies the allegations in Paragraph 202 of the Complaint.

203. Par denies the allegations in Paragraph 203 of the Complaint.

**COUNT VIII**  
**(CONSPIRACY TO MONOPOLIZE – NEW JERSEY ANTITRUST ACT)**

204. Par reasserts its answers to Paragraphs 1 through 203 of the Complaint.

205. Par denies the allegations in Paragraph 205 of the Complaint.

206. Par denies the allegations in Paragraph 206 of the Complaint.

207. Par denies the allegations in Paragraph 207 of the Complaint.

208. Par denies the allegations in Paragraph 208 of the Complaint.

209. Par denies the allegations in Paragraph 209 of the Complaint.

210. Par denies the allegations in Paragraph 210 of the Complaint.

211. Par denies the allegations in Paragraph 211 of the Complaint.

**COUNT IX**  
**(EXCLUSIVE DEALING – NEW JERSEY ANTITRUST ACT)**

212. Par reasserts its answers to Paragraphs 1 through 211 of the Complaint.

213. Par denies the allegations in Paragraph 213 of the Complaint.

214. Par denies the allegations in Paragraph 214 of the Complaint.

215. Par denies the allegations in Paragraph 215 of the Complaint.

216. Par denies the allegations in Paragraph 216 of the Complaint.

217. Par denies the allegations in Paragraph 217 of the Complaint.

218. Par denies the allegations in Paragraph 218 of the Complaint.

219. Par denies the allegations in Paragraph 219 of the Complaint.

**COUNT X**  
**(UNLAWFUL GROUP BOYCOTT – NEW JERSEY ANTITRUST ACT)**

220. Par reasserts its answers to Paragraphs 1 through 219 of the Complaint.

221. Par denies the allegations in Paragraph 221 of the Complaint.

222. Par denies the allegations in Paragraph 222 of the Complaint.

223. Par denies the allegations in Paragraph 223 of the Complaint.

224. Par denies the allegations in Paragraph 224 of the Complaint.

225. Par denies the allegations in Paragraph 225 of the Complaint.

226. Par denies the allegations in Paragraph 226 of the Complaint.

227. Par denies the allegations in Paragraph 227 of the Complaint.

228. Par denies the allegations in Paragraph 228 of the Complaint.

229. Par denies the allegations in Paragraph 229 of the Complaint.

**COUNT XI**  
**(TORTIOUS INTERFERENCE WITH PROSPECTIVE ECONOMIC ADVANTAGE)**

230. Par reasserts its answers to Paragraphs 1 through 229 of the Complaint.

231. Par denies the allegations in Paragraph 231 of the Complaint.

232. Par denies the allegations in Paragraph 232 of the Complaint.

233. Par denies the allegations in Paragraph 233 of the Complaint.

234. Par denies the allegations in Paragraph 234 of the Complaint.

235. Par denies the allegations in Paragraph 235 of the Complaint.

236. Par denies the allegations in Paragraph 236 of the Complaint.

237. Par denies the allegations in Paragraph 237 of the Complaint.

### **JURY DEMAND**

238. Par admits that Plaintiff seeks trial by jury on issues so triable.

### **PRAYER FOR RELIEF**

Par denies the allegations of the Prayer for Relief including each subpart, and avers that Plaintiff is entitled to no relief.

### **PAR'S AFFIRMATIVE DEFENSES**

Par incorporates by reference into each of the defenses below, as if fully set forth therein, its responses to the allegations contained in Paragraphs 1 through 238 of the Complaint, as set forth above. Par reserves its right to amend its Answer to assert additional defenses as they may become known during discovery.

By alleging these defenses, Par is not agreeing or conceding that it has the burden of proof on any of the issues raised in these defenses, or that any particular issue or subject matter herein is relevant to Plaintiff's allegations.

1. Plaintiff lacks standing to bring the claims raised in the Complaint.
2. The Complaint fails to state a claim upon which relief can be granted.
3. Plaintiff suffered no injury caused by or attributable to the conduct of

Par.

4. Plaintiff's claims are barred in whole or in part by the applicable statutes of limitations.

5. Plaintiff's claims are barred in whole or in part by the doctrine of laches.

6. Plaintiff's claims are barred because it has not sustained any cognizable antitrust injury attributable to Par's conduct.

7. Plaintiff's claims are barred in whole or in part because Plaintiff failed to mitigate its alleged damages, if any.

8. Plaintiff's claims are barred in whole or in part by the doctrines of waiver and/or estoppel.

9. Plaintiff has suffered no damages.

10. Any damages allegedly suffered by Plaintiff are speculative.

11. Plaintiff's claims are barred because the alleged conduct was unilateral, has not unreasonably restrained trade, was based on independent and legitimate business and economic justifications, and constituted lawful, bona fide business behavior.

12. The Complaint fails to allege sufficiently or otherwise properly define any market for the purpose of asserting a claim against Par.



13. Plaintiff's claims are barred in whole or in part because the acts or omissions of Par did not substantially lessen competition in any properly defined market.

14. Plaintiff's claims are barred in whole or in part because Par did not engage in predatory or anticompetitive conduct.

15. Plaintiff's claims are barred in whole or in part because Par did not engage in any activity with the specific intent to monopolize.

16. Plaintiff's claims are barred in whole or in part because Par did not act with the specific intent to monopolize.

17. Plaintiff's claims are barred in whole or in part because any award of treble damages or punitive or exemplary damages against Par based on the alleged conduct would violate the Due Process Clauses of the Fifth and Fourteenth Amendments of the Constitution of the United States.

18. Plaintiff's claims are barred in whole or in part by the First Amendment to the United States Constitution and the *Noerr-Pennington* doctrine.

19. To the extent any actionable conduct occurred, Plaintiff's claims are barred to the extent that such conduct was committed by an individual acting ultra vires.

20. Plaintiff has failed to state a claim for injunctive relief insofar as Plaintiff seeks to enjoin alleged events that already have transpired without the requisite showing of threatened harm or continuing harm.

21. The foregoing defenses are raised by Par without waiver of any other defenses that may become known during the discovery proceedings in this case or otherwise. Par hereby reserves the right to amend or supplement its Answer to assert any other related defenses as they become available.

WHEREFORE, Par prays that the Court determine and adjudge:

- (a) that the Complaint should be dismissed on the merits;
- (b) that Plaintiff takes nothing by the Complaint;
- (c) that Par be awarded its costs, disbursements, attorney's fees, and expenses incurred herein; and
- (d) that Par be awarded such other and further relief as the Court may deem proper.

**DEMAND FOR JURY TRIAL**

Par demands trial by jury on all issues that may properly be submitted to a jury.

Dated: March 10, 2017

Respectfully submitted,

/s/ Thomas R. Curtin

Thomas R. Curtin  
George C. Jones  
GRAHAM CURTIN  
A Professional Association  
4 Headquarters Plaza  
P.O. Box 1991  
Morristown, New Jersey 07962-1991  
Tel: (973) 292-1700  
Fax: (973) 292-1767  
tcurtin@GrahamCurtin.com  
gjones@GrahamCurtin.com

Edward D. Hassi  
Stephen D. Brody  
O'MELVENY & MYERS LLP  
1625 Eye St., N.W.  
Washington, D.C. 20006  
Phone: (202) 383-5300  
Fax: (202) 383-5414  
ehassi@omm.com  
sbrody@omm.com

Michael F. Brockmeyer  
HAUG PARTNERS LLP  
1667 K Street N.W.  
Suite 500  
Washington, D.C. 20006  
Tel: (202) 292-1545  
Fax: (202) 292-1531  
mbrockmeyer@haugpartners.com

*Attorneys for Defendants  
Par Sterile Products, LLC and  
Par Pharmaceutical Companies, Inc.*